Cholestech LDX®

System Procedure Manual

CHOLESTECH

Table of Contents

Foreword – Procedure Manual Overview . . . . . *iii*
Introduction – Overview of a Quality Assurance Program . . . . . *iv*

1.0 Setup and Maintenance
1.1 Introduction 2
1.2 Cholestech LDX Optics Check Cassette 2
1.3 Optics Check Cassette Test Procedure 2
1.4 Environmental Requirements 3
1.5 Laboratory Temperature Records 3
1.6 Instrument History Record 3
1.7 Cholestech LDX System Initial Setup 4
1.8 Maintenance and Cleaning of the Cholestech LDX System 4
1.9 Course of Action If System Becomes Inoperable 5
1.10 *Procedure Sign-Off* 6
1.11 Reference(s) and Bibliography 6

2.0 Specimen Collection and Handling
2.1 Introduction 8
2.2 Fingerstick Procedure 8
2.3 *Procedure Sign-Off* 9
2.4 Venipuncture Procedure 10
2.5 *Procedure Sign-Off* 12
2.6 Reporting Results Properly 12
2.7 *Procedure Sign-Off* 13
2.8 Proper Specimen Storage 14
2.9 Procedure to Properly Remove a Rubber Stopper from an Evacuated Tube 15
2.10 Reference(s) and Bibliography 15

3.0 Quality Control
3.1 Introduction 18
3.2 Quality Control Materials 18
3.3 Frequency of Testing 18
3.4 Establishing and Calculating a Control Range 19
3.5 Cholestech LDX System Quality Control Log 20
3.6 When Results Are Outside Acceptable Control Limits 20
3.7 Quality Control Remedial Action 20
3.8 *Procedure Sign-Off* 21
3.9 Reporting a Complaint 21
3.10 *Procedure Sign-Off* 22
3.11 Cholestech LDX System Calibration Verification and Linearity Testing 22
3.12 Reference(s) and Bibliography 23

4.0 Safety
4.1 Introduction 26
4.2 Reference(s) and Bibliography 26

5.0 Training
5.1 Introduction 28
5.2 Cholestech LDX Training Checklist 28
5.3 Certificate of Training – Fingerstick Blood Collection 28
5.4 Online Training 28

6.0 Material Safety Data Sheets 30

7.0 Proficiency Testing
7.1 Overview of Proficiency Testing 34
7.2 Proficiency Testing Agencies 36
7.3 Reference(s) and Bibliography 36

8.0 Glossary of Terms 38
8.1 Reference(s) and Bibliography 43

9.0 Master Forms 45
Optics Check Log
Temperature Chart
Instrument History Record
Information and Service Log
Initial Setup Checklist
Equipment Maintenance/Cleaning Log
Instruments In-Use Record
Patient Result Log
Patient Result Label Log No. 1
Patient Result Label Log No. 2
Quality Control Log No. 1
Quality Control Log No. 2
Quality Assurance Record
Control Range Calculation Form
Accuracy Study Data
Precision Calculation Form
Training Checklist
Certificate of Training for Fingerstick Blood Collection

Test Cassette Inserts
Test Procedure – Lipid Profile·GLU
Test Procedure – ALT

Foreword

Procedure Manual Overview

This procedure manual has been designed to instruct Cholestech LDX users in how to comply with good laboratory practices and assist in complying with applicable regulations.

The Cholestech LDX System Procedure Manual covers:

- Setup and Maintenance: Procedure to properly run an optics check and record the values for the Cholestech LDX System. In addition, the section provides specific information about recording laboratory environmental conditions.
- Specimen Collection and Handling: General procedures that are applicable to obtaining a suitable specimen and running a test on the Cholestech LDX System.
- Quality Control: Discusses laboratory activities designed to ensure that each test system is working properly and that the test results satisfy quality standards.
- Safety: Allows you to file your safety guidelines as recommended by OSHA.
- Training: A checklist as a guideline to train personnel on the Cholestech LDX System. After the training is completed, you may use the Certificate of Training for the Cholestech LDX System and the Certificate of Training for Fingerstick Blood Collection to document training.
- Material Safety Data Sheets: A copy of Cholestech Corporation's MSDS for the Cholestech LDX test cassettes. You can add additional MSDSs as required.
- Proficiency Testing Guidance: Discusses the importance of proficiency testing, how testing is performed and lists agencies offering proficiency testing.
- Glossary of Terms: An alphabetical list of common laboratory terms.
- Master Forms: Master forms are provided for you to print as needed.

An icon, characterized as a letter within a shape, will appear at the beginning of each section. These icons indicate the following:

I The information in this section is "For Information Only."

R The information in this section is "Recommended" by the Manufacturer.

O The information in this section is recommended to comply with OSHA and CLIA '88 Moderately Complex Laboratory Regulations, as well as regulations that apply to users in certain states.

If you need assistance using the manual, please call us at 800-733-0404.

Please Note: The following procedures are outlined as a guide, not a substitute for complying with state or federal regulations relevant to your site. Cholestech Corporation does not guarantee that following this guide will result in certification or meeting state or federal regulations. For further information regarding regulations, please refer to your state or federal agencies.

Introduction

Overview of a Quality Assurance Program

Quality assurance (QA) is a comprehensive set of policies, procedures and practices necessary to ensure the quality of laboratory tests. Its purpose is to ensure that over the long term, the laboratory provides reliable data that accurately reflect the patient's status. Quality assurance in a point-of-care laboratory covers nine basic areas:

1. Policies and standards that govern the laboratory cover elements that affect test quality before (patient preparation, sample collection, etc.), during and after (data transcription errors, etc.) the testing process.

2. Training: All personnel conducting tests should be properly trained and their training documented.

3. Safety policies should be adhered to and a safe working environment provided.

4. Procedure manuals should contain operating protocols that are complete, up to date and available to laboratory personnel.

5. Record keeping: All aspects of the quality assurance program should be documented in writing as appropriate.

6. Calibration and instrument maintenance should be performed as needed.

7. Quality control may include initial verification of the test method, routine testing of quality control materials and a written procedure for responding to "out of control" test results. All quality control procedures and follow-up actions should be documented.

8. Participation in proficiency testing programs is optional for CLIA-waived tests. Proficiency testing may be performed and documented when required by local or state regulations.

9. Laboratory inspections may be conducted by the appropriate organization to assess quality assurance and suggest possible improvements.

A successful QA program assures that:

1. Policies and procedures are established in writing and followed by all personnel involved in the testing process.

2. The test system performs properly at the time patient results are produced.

3. Written records are available to demonstrate that uniform procedures have been established and are followed.

The material in this procedure manual can assist in assuring that the quality of test results in the laboratory or at a testing site is satisfactory over time.

1.0 Setup and Maintenance

< TABLE OF CONTENTS

Setup and Maintenance

1.1 Introduction

This section contains the procedure to properly run an optics check and specific information about proper maintenance. A sample copy of each form referred to is included in the *Master Forms* section of this manual.

1.2 Cholestech LDX Optics Check Cassette

A Cholestech LDX Optics Check Cassette with known reflectance values is supplied with each Analyzer. It should be used to check the optical system of the Analyzer. Store the Cholestech LDX Optics Check Cassette at room temperature in the case provided. Do not touch the reaction bar or allow it to become wet, dirty or scratched. Do not use a damaged or expired Cholestech LDX Optics Check Cassette.

Run a Cholestech LDX Optics Check Cassette:

- Once each day before patient samples are tested.
- After the Cholestech LDX System has been moved or serviced.

1.3 Optics Check Cassette Test Procedure

Do not use a Cholestech LDX Optics Check Cassette that is expired, damaged or altered in any way.

1. Press the **RUN** button. After verifying the "Selftest OK" message, the drawer will open, and the screen will display:

```
Load cassette
and press RUN
```

2. Place the Optics Check Cassette into the cassette drawer.

Do not place any blood sample on the cassette.

3. Press the **RUN** button again and the Analyzer will automatically perform the optics check. The words Optics Check and four numbers will appear on the screen, one for each optical channel in the Analyzer.

```
Optics Check
##-##-##-##
ch#1-ch#2-ch#3-ch#4
```

4. If the numbers for all four channels fall within the ranges printed on the Optics Check Cassette label, the system is ready for use.

5. If the numbers for any of the four channels fall outside the ranges printed on the Optics Check Cassette label, the Analyzer will shut down. The Analyzer will be disabled until another optics check has been run that falls within range. Try running an optics check with a different Optics Check Cassette. If the numbers are still outside the range, call Cholestech Technical Service at 800-733-0404.

6. Record the results in the **Optics Check Log** each day.

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1.4 Environmental Requirements

Operating Voltage
- +9 volt DC at 1 amp

Environmental Conditions
- Indoor use
- Altitude up to 2000 meters
- Temperature 20ºC - 31ºC (68ºF - 87ºF)
- Relative humidity 80% for temperature up to 31ºC decreasing linearly to 50% relative humidity at 40ºC
- PollutionDegree Class Two

If the temperature or light requirements are not acceptale, the Analyzer will shut down until they are met

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1.5 Laboratory Temperature Records

Forms are included in this manual (see *Master Forms* section) to record the temperature of the laboratory room and refrigerator. Each form is designed for a daily record to be made. There is space for the site identification, the acceptable temperature range and daily temperature records. Record the temperature and your initials in the allocated spaces.

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1.6 Instrument History Record

Proper, continuing care for a laboratory instrument has primary importance, as it minimizes breakdowns and ensures proper results.

The **Instrument History Record** allows lab personnel to communicate effectively with Cholestech Technical Service. You should have a record for your Cholestech LDX System as well as records for any other instruments in the lab.

Several general guidelines are helpful in ensuring satisfactory preventive maintenance:

- Select one person to have principal responsibility for a given instrument.
- Make sure that this person is familiar with the user manual, the procedure manual, and the package inserts for each test system.
- Perform all required preventive maintenance called for in the Cholestech LDX System User Manual and keep a record of it. Record the date, type of maintenance done, and the name or initials of the person doing the maintenance.
- Keep all spare parts recommended by the manufacturer on hand.

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1.7 Cholestech LDX System Initial Setup

The **Initial Setup Checklist** is provided to assure that all of the environmental conditions are met and that the Cholestech LDX System runs properly during the initial setup in the laboratory.

The **Instrument History Record** can be used to record any service performed on the Cholestech LDX System or other instruments in your laboratory. Both forms can be found in the *Master Forms* section of this manual.

Cholestech Corporation will provide technical support to each Cholestech LDX System user. Any questions regarding the operation of the Cholestech LDX System may be directed to:

Cholestech Corporation
Technical Service Department
3347 Investment Boulevard
Hayward, CA 94545 U.S.A.
Tel 800 733.0404
Fax 510 732.7227
www.cholestech.com
techservice@cholestech.com

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1.8 Maintenance and Cleaning of the Cholestech LDX System

No maintenance is required other than routine cleaning when necessary.

- Clean the outside of the Cholestech LDX Analyzer case with a clean, damp, non-abrasive cloth. Most spills and stains will be removed with water or a mild detergent. A solution of 70% isopropyl alcohol, or 5% bleach, or any nonstaining, commercially available disinfectant are all appropriate cleaning agents. Do not immerse the instrument in water or other cleaning fluid. Do not use any abrasive cleanser.
- When necessary, clean the cassette drawer with a cotton swab moistened with water, a 70% isopropyl alcohol solution, 5% bleach or disinfectant. Dry with a second cotton swab.

You can record maintenance and cleaning performed on the Cholestech LDX System and other instruments in your laboratory on the **Equipment Maintenance/Cleaning Log** in the *Master Forms* section of this manual.

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1.9 Course of Action If System Becomes Inoperable

Course of Action for the Cholestech LDX System

If the Cholestech LDX System becomes inoperable, call Cholestech Technical Service at 800-733-0404 or 510-732-7200. Until the instrument becomes operable, venous specimens will be drawn and sent to the following reference laboratory.

Laboratory Name _____

Laboratory Address _____

_____

_____

Laboratory Phone No. _____

or

An alternative Cholestech LDX Analyzer will be used.

Course of Action for Other Instruments in the Lab

Name of Instrument _____

Technical Service Phone Number _____

Written Procedure If the Instrument Fails _____

_____

_____

Course of Action for Other Instruments in the Lab

Name of Instrument _____

Technical Service Phone Number _____

Written Procedure If the Instrument Fails _____

_____

_____

1.10 Procedure Sign-Off

Approved

Director's Signature Date

Adopted

Director's Signature Date

Revised

Director's Signature Date

Discontinued

Director's Signature Date

The procedure is not applicable to this laboratory:

Director's Signature Date

1.11 Reference(s) and Bibliography

1. National Committee for Clinical Laboratory Standards. *Physician's Office Laboratory Procedure Manual; Tentative Guideline*. Villanova, Pa.: NCCLS; 1989. NCCLS publication POL2-T, Vol. 12, No. 5.

2.0 Specimen Collection and Handling

< TABLE OF CONTENTS

Specimen Collection and Handling

2.1 Introduction

Since the collection of the patient's specimen is the beginning of the analytical process, the use of proper collection techniques is essential to obtaining accurate results. It is imperative that laboratories follow appropriate biohazard and safety procedures.

Many laboratory errors can be traced to such nonanalytical factors as misidentifying or mishandling specimens. Nonanalytical error can be prevented by using careful collection and processing procedures.

Several factors can influence a result so that it does not reflect the patient's usual cholesterol level. Many of these variations are due to things that occur before or during blood collection, or during the time the blood is stored or shipped to the laboratory. It is important to understand and control these factors as much as possible to get accurate results.

Factors that contribute to the patient's usual cholesterol level include:

- Age and gender
- Within-day variation
- Seasonal variation
- Diet and alcohol
- Exercise
- Drugs
- Fasting
- Posture
- Venous occlusion
- Recent heart attack or stroke
- Trauma and acute infection
- Pregnancy

For more information on patient variables, please contact Cholestech Technical Service at 800-733-0404.

2.2 Fingerstick Procedure

Precautions

When handling patient samples, appropriate biohazard precautions should be taken.

A warm hand and good blood flow from the puncture site are essential to draw a good capillary sample.

1. **The patient should sit quietly for five minutes before the blood sample is collected.**

2. Put a capillary plunger into a Cholestech capillary tube at the end with the red mark. Set it aside.

3. Choose a spot on the side of one of the *center* fingers of either hand. The fingers and hands should be warm to the touch. To warm the hand, you can:
   a. Wash the patient's hand with warm water, or...
   b. Apply a warm (not hot) compress to the hand for several minutes, or...
   c. Gently massage the finger from the base to the tip several times to bring the blood to the fingertip.

4. Clean the site with an alcohol swab. **Dry thoroughly before pricking the finger.**

5. Firmly prick the selected site with a lancet.

6. Squeeze the finger gently to obtain a large drop of blood. Wipe away this first drop of blood as it may contain tissue fluid.

7. Squeeze the finger gently again while holding it downward until a second large drop of blood forms. **Do not milk the finger.** The puncture should provide a free-flowing drop of blood.

8. Hold the capillary tube horizontally by the end with the plunger. Touch it to the drop of blood without touching the skin. The tube will fill by capillary action up to the black mark. **Do not collect air bubbles.** If it is necessary to collect another drop of blood, wipe the finger with gauze then massage again from base to tip until a large drop of blood forms.

9. Wipe off any excess blood and have the patient apply pressure to the puncture until the bleeding stops.

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2.3 Procedure Sign-Off

Approved _____
Director's Signature Date

Adopted _____
Director's Signature Date

Revised _____
Director's Signature Date

Discontinued _____
Director's Signature Date

The procedure is not applicable to this laboratory:

_____
Director's Signature Date

I For Information Only R Recommended O Optional Information

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2.4 Venipuncture Procedure

Precautions

This procedure should be conducted only by a qualified phlebotomist. When handling patient samples, follow appropriate biohazard precautions.

Venipuncture Setup

1. Identify appropriate specimen type/types for the tests you are performing:

   - **Whole blood** – Anticoagulated whole blood containing white blood cells, red blood cells, platelets, and plasma.
   - **Serum** – The liquid part of the blood obtained after the blood has been allowed to coagulate and then spun down in a centrifuge. Red blood cells and fibrin are separated from the rest of the liquid.
   - **Plasma** – The liquid part of the blood obtained after the specimen has been mixed with an anticoagulant and then spun down in a centrifuge. Cellular components are separated from the rest of the liquid.

2. Select appropriate tubes and needles needed for the tests.

COLOR-CODED TUBES

Color	Use	Additive
Green*	**Plasma or Whole Blood**	**Heparin**
Red	Serum	None
Red or Red/Black	Serum	Serum separator gel

Please Note: The Cholestech LDX System is CLIA-waived for fingerstick or venous whole blood unprocessed samples only. If you run serum or plasma on the Cholestech LDX, you will be classified as moderately complex and will have to comply with the regulations for moderate complexity. See the Cholestech LDX System User Manual for a summary of these regulations.

3. When collecting several samples during a venipuncture, start with the tubes that have no additive, or a serum separator tube.

*** This is the appropriate tube for use with the Cholestech LDX System.**

Performing the Venipuncture

1. Identify the patient by asking the patient to state his/her full name.
2. Label the tube with the patient's name or identification number.
3. Reassure the patient to make him or her comfortable.
4. Have the patient make a fist to increase blood flow.
5. Apply the tourniquet. Do not stop blood flowing in the veins for more than a minute before the blood is drawn as it causes venous occlusion. If necessary, release the tourniquet and reapply. Leaving the tourniquet on for more than three minutes may cause erroneous results.

I For Information Only R Recommended O Optional Information

6. Select the venipuncture site.

7. Clean the venipuncture site with a 70% isopropyl alcohol pad, making one smooth circular pass of the venipuncture site.

8. Allow the skin to dry to prevent hemolysis of the specimen and to prevent the patient from having a burning sensation when the venipuncture is performed. **Do not touch the venipuncture site after cleaning it.**

9. Perform the following procedure:

   - Grasp the patient's arm near the venipuncture site using your thumb to draw the skin tight.
   - With the needle bevel facing up, line up the needle with the vein. Penetrate the skin and enter the vein at an angle of approximately 45º.
   - Holding the flange of the needle holder, push the tube forward until the back end of the needle punctures the stopper. While the needle is in the vein, keep the tube below the puncture site.
   - When the blood starts flowing into the tube, release the tourniquet and open the patient's hand. This allows circulation to return to normal and reduces bleeding at the venipuncture site. When drawing multiple tubes, keep the tourniquet in place until the last tube is being collected.
   - Keep constant, forward pressure on the tube (in the direction of the needle); this prevents the shutoff valve from closing and stopping the flow of blood.
   - When the blood stops flowing, remove the tube from the holder. The needle's shutoff valve will stop the blood flow until the next tube is inserted.
   - Tubes containing an anticoagulant should be allowed to fill until the vacuum is exhausted and blood flow ceases (this assures the correct ratio of anticoagulant to blood volume). Gently invert the tube five to ten times to mix the blood and anticoagulant. **Do not shake the tube vigorously.**
   - Insert the next tube into the holder and repeat the collection procedure.

If a blood sample cannot be obtained, change the position of the needle. If the needle has penetrated too far into the vein, pull it back a bit. If it has not penetrated far enough, move it farther into the vein. If this does not help, try inserting another evacuated tube.

10. Remove the needle, apply pressure and bandage the site.

    - After the tube has been withdrawn from the holder, gently remove the needle from the venipuncture site. Immediately apply a sterile gauze pad to the site, and tell the patient to keep pressure on the site for two minutes.
    - Apply an adhesive or gauze bandage over the venipuncture site after the bleeding has stopped. The patient should leave the bandage on for a minimum of 15 minutes.

11. Dispose of the puncture unit. To prevent injury and to be sure needles are not reused, promptly dispose of the needle and the blood tube holder in an appropriate biohazard container. *Do not recap the needle.*

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2.5 Procedure Sign-Off

Approved _____
Director's Signature Date

Adopted _____
Director's Signature Date

Revised _____
Director's Signature Date

Discontinued _____
Director's Signature Date

The procedure is not applicable to this laboratory:

_____
Director's Signature Date

O

2.6 Reporting Results Properly

You may wish to establish a procedure that will prevent any misidentification when giving the results to the physician or patient. The following space is available to record the laboratory procedure that will be used to report results from the Cholestech LDX System. Or you may use the **Patient Result Log** in the *Master Forms* section.

The additional space that follows is available to document the procedures for other instruments in the laboratory.

Cholestech LDX System _____

_____

_____

_____

_____

Instrument Name Manufacturer

_____

_____

_____

_____

I For Information Only R Recommended O Optional Information

Instrument Name	Manufacturer

O

2.7 Procedure Sign-Off

Approved

Director's Signature Date

Adopted

Director's Signature Date

Revised

Director's Signature Date

Discontinued

Director's Signature Date

The procedure is not applicable to this laboratory:

Director's Signature Date

I For Information Only R Recommended O Optional Information

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2.8 Proper Specimen Storage

1. Anticoagulated blood may be sampled directly from the tube after mixing. This step should be performed within 30 minutes of collection. Use a MiniPet™ Pipette and tips or a micropipetter calibrated to deliver 35 µL. Do not use the Cholestech capillary tubes for transferring venous whole blood, serum or plasma to a Cholestech LDX test cassette.

2. Glucose levels decrease due to glycolysis at the rate of 5 to 10 mg/dL per hour in whole blood at room temperature.[3]

3. Serum samples should be allowed to clot for 30 minutes and then centrifuged. Serum should be separated from the blood cells and stored refrigerated in a tightly sealed sample tube at 36–46°F (2–8°C) until a test is performed.

4. When plasma samples are used, plasma should be separated from the blood cells within 30 minutes of collection and stored refrigerated in a tightly sealed sample tube at 36–46°F (2–8°C) until the test is performed.[5]

5. If using serum or plasma samples to evaluate or validate the Cholestech LDX System, the following information should be considered: Cholesterol levels are stable in serum or plasma for 4 days at 36–46°F (2–8°C) or for 3 months at –4°F (–20°C). HDL cholesterol levels are stable in serum or plasma samples for up to 24 hours when stored at 36–46°F (2–8°C) or up to 2 weeks when stored at –4°F (–20°C). Triglyceride levels are stable in serum or plasma samples for 7 days when stored at 36–46°F (2–8°C) or for 3 months when stored at –4°F (–20°C).[3] Glucose is stable in serum samples for up to 8 hours at 77ºF (25°C), or up to 72 hours at 36–46°F (2–8°C) when the serum separated from the blood cells is unhemolyzed and kept free of bacterial contamination.[3] Minimal loss of ALT and AST activity occurs when serum samples are stored up to 2 days at 36–46ºF (2–8°C). Serum samples should be stored frozen if they are to be kept more than 3–4 days.[6]

6. Serum and plasma samples should be brought to room temperature before the test is performed.

7. Mix all samples thoroughly by gentle inversion 7–8 times before testing.

I For Information Only R Recommended O Optional Information

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2.9 Procedure to Properly Remove a Rubber Stopper from an Evacuated Tube

1. All blood samples and blood products are potentially biohazardous and should be treated as such. Gloves, goggles and a completely buttoned long-sleeve lab coat should be worn when handling these materials.

2. When removing rubber stoppers from evacuated tubes, cover the stopper with a piece of gauze, or remove with an evacuated tube stopper remover.

3. Always point the tops of any sample tubes away from anyone when removing the caps. Pipette tips are pointed away from people while the tips are being ejected.

4. For cleanup of spilled blood and blood products, observe the safety policies in the lab and the Universal Precautions recommended by the Occupational Safety & Health Administration (OSHA).

I

2.10 Reference(s) and Bibliography

1. National Committee for Clinical Laboratory Standards. *Physician's Office Laboratory Procedure Manual; Tentative Guideline*. Villanova, Pa.: NCCLS; 1989. NCCLS publication POL2-T, Vol. 12, No. 5.

2. National Committee for Clinical Laboratory Standards. *Procedure for the Collection of Diagnostic Blood Specimens by Skin Puncture*. 2nd ed. Approved Standards, NCCLS.

3. Tietz NW, ed. *Fundamentals of Clinical Chemistry*. Philadelphia, Pa.: WB Saunders Co; 1987.

4. National Committee for Clinical Laboratory Standards. *Protection of Laboratory Workers from Infectious Disease Transmitted by Blood, Body Fluids, and Tissue; Tentative Guideline*. Villanova, Pa.: NCCLS; 1991. NCCLS document M29-T2 (ISBN 1-56238-123-7).

5. Davidsohn I, Henry JB, eds. *Todd-Sanford Clinical Diagnosis by Laboratory Methods*. Philadelphia, Pa.: WB Saunders Co; 1969.

6. Burtis CA, Ashwood ER, eds. *Tietz Textbook of Clinical Chemistry*. 3rd ed. Philadelphia, Pa.: WB Saunders Co; 1999.

3.0 **Quality Control**

< TABLE OF CONTENTS

Quality Control

R

3.1 Introduction

Quality control is the specific set of laboratory activities designed to ensure that the test system is working properly and that test results satisfy quality standards. Quality control data must be kept as permanent records to document the performance of laboratory testing.

Documentation includes written laboratory records that are a clear and up-to-date compilation of quality control data. These records may be in the form of daily worksheets or logs. The person performing the test should sign and date the log sheets.

We have provided you with a **Quality Control Log** that you can duplicate and use for recording quality control test results for the Cholestech LDX System. As an alternative, we have also supplied a **Daily Quality Assurance Record** that can be used to record all routine quality control documentation. The originals are in the *Master Forms* section of this manual.

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3.2 Quality Control Materials

Control materials should be provided for at least two levels of total cholesterol, HDL cholesterol, triglycerides, glucose, ALT and AST.

Choice of Material

The preferred quality control material for use with the Cholestech LDX System is Cholestech LDX Level 1 and Level 2 Control Materials. If you choose to use an alternate quality control material, see Section 3.4.

Handling of Material

- Follow the instructions for preparation, handling and storage that accompany each lot of control material.
- Check the expiration date before use. Do not use the control material beyond the expiration date.
- Mix quality control material by gentle inversion 7–8 times before use.
- Check the control assay sheet for the correct sample setting for running controls.
- Verify that the lot number on the control vial and the assay sheet are the same.

R

3.3 Frequency of Testing

Liquid Level 1 and Level 2 Controls are available from Cholestech. Controls must be tested:

- With each new shipment of cassettes (even if cassettes are from the same lot previously received).
- With each new lot of cassettes.
- As otherwise required by your laboratory's standard quality control procedures.
- If you are not running the Cholestech LDX under CLIA-waived status, or if your local or state regulations require more frequent testing of quality control material, then quality control must be performed in compliance with those regulations.

I For Information Only R Recommended O Optional Information

Good laboratory practice principles suggest that external controls must be run whenever the laboratory director has any question about test system integrity or operator technique (e.g., when reagents may have been stored or handled in a way that can degrade their performance or when operators have not performed a particular test in recent weeks).

If the controls do not perform as expected, repeat the test or contact Cholestech Technical Service before testing patient samples.

The quality control results must be in range before testing patient samples. See the Cholestech LDX System User Manual if they are not.

Please call Cholestech Technical Service at 800-733-0404 if you have any questions regarding the manufacturer's instructions for quality control.

3.4 Establishing and Calculating a Control Range

If the control materials you plan to use do not have ranges set for the Cholestech LDX, or if you prefer to set your own ranges, please follow this procedure. Before you start, order an adequate supply of control materials to last you several months. Do not order more than you will use before the expiration date. You will need to follow this procedure to set ranges for each level of control you use, and for each analyte you test for.

1. For each analyte, test a minimum of 20 replicates for each level of control material on the Cholestech LDX. Record each result on the form provided.
   a. Use one **Control Range Calculation Form** for each analyte and control level.
   b. Assure all information is completed at the top of the data collection form.
   c. If more than one Cholestech LDX Analyzer is in use in the laboratory, they should all be used in determining the control range. The total number of results included in the calculation should be at least 20, evenly run across the Analyzers.

2. You may calculate the statistics manually using the form provided by Cholestech or you can use a statistical calculator computer program to do the calculations.

   If you prefer, you can send or fax your results to Cholestech Technical Service at 800-733-0404, fax 510-732-7227. We will perform the calculations for you and send the results and data calculations back to you.

3. Your control range should be set as the mean value plus or minus two standard deviations (rounded off to the nearest integer).

   For example: If you calculate the mean to be 175 mg/dL and the standard deviation to be 3.9 mg/dL, your acceptable control range would be:

   175 mg/dL ± 8 mg/dL, or **167–183 mg/dL.**

4. Record this control range on the Quality Control Log for that analyte, level and lot number of control material.

5. When you run quality control samples, the results you get should fall within this range. If the value of the control is outside these limits, then testing is considered to be out of control.

The quality control results must be in range before testing patient samples. See the Cholestech LDX System User Manual if they are not.

6. If results for all levels of quality control material are within established ranges, patient samples may be tested and the results reported.

7. When you change lot numbers of control materials, you will need to repeat this procedure.

R

3.5 Cholestech LDX System Quality Control Log

R

We have provided you with a log sheet that can be duplicated and used for your records when you test quality control materials on the Cholestech LDX System. (See *Master Forms* section.)

3.6 When Results Are Outside Acceptable Control Limits

If results of one or both levels of control tested are outside established ranges:

1. Check that the expiration date for the test cassette and quality control materials have not passed.

2. Verify that the lot number on the control vial and the assay sheet are the same.

3. Retest the control level that is out of range using a new sample from the same control vial. Pay careful attention to possible errors in technique.
   a. If the control is within acceptable limits, patient samples may be tested and results reported.
   b. If the control is outside acceptable limits, retest with a sample of control from a new vial.
      - If results are in range, continue testing patient samples.
      - If the control is still outside acceptable limits, contact Cholestech Technical Service at 800-733-0404. Do not use the Analyzer for testing patient samples until the problem is resolved.

O

3.7 Quality Control Remedial Action

Use this space if you wish to document a course of remedial action should any erroneous results occur. The action will be initiated if a patient has received test results during the time in which the instrument control results were out of range.

Procedure

For Information Only R Recommended O Optional Information

O

3.8 Procedure Sign-Off

Approved _____
Director's Signature Date

Adopted _____
Director's Signature Date

Revised _____
Director's Signature Date

Discontinued _____
Director's Signature Date

The procedure is not applicable to this laboratory:

_____
Director's Signature Date

O

3.9 Reporting a Complaint

Use this space if you wish to document the action taken when a patient complains of receiving erroneous test result(s).

Procedure

O

3.10 Procedure Sign-Off

Approved

Director's Signature Date

Adopted

Director's Signature Date

Revised

Director's Signature Date

Discontinued

Director's Signature Date

The procedure is not applicable to this laboratory:

Director's Signature Date

O

3.11 Cholestech LDX System Calibration Verification and Linearity Testing

This procedure meets requirements for calibration verification and linearity testing.

To verify calibration for the Cholestech LDX System, a linearity test is performed with a minimum of three samples over the measuring range for each analyte to be tested on the instrument.

The samples can be sera collected by the user that have test values set by an accepted reference method. Alternately, materials to verify the instrument calibration and cassettes are commercially available.

Each sample is tested in duplicate and the results averaged. Results are evaluated by a regression analysis or the manufacturer of the calibration verification material may give acceptable ranges for results.

Contact Cholestech Technical Service at 800-733-0404 for recommended calibration verification material.

3.12 Reference(s) and Bibliography

1. National Committee for Clinical Laboratory Standards. *Physician's Office Laboratory Procedure Manual; Tentative Guideline*. Villanova, Pa.: NCCLS; 1989. NCCLS publication POL2-T, Vol. 12, No. 5.

2. Westgard JO, et al. Concepts and practices in the evaluation of clinical chemistry methods II: experimental procedures. *American Journal of Medical Technology* 1978; 44:420–30.

3. National Committee for Clinical Laboratory Standards. *Physician's Office Laboratory Guidelines; Tentative Guidelines*. Villanova, Pa.: NCCLS; 1989. NCCLS publication POL1-T.

4. National Committee for Clinical Laboratory Standards. *User Comparison of Quantitative Clinical Laboratory Methods Using Patient Samples; Proposed Guideline*. Villanova, Pa.: NCCLS; 1986. NCCLS publication EP9-P.

5. National Committee for Clinical Laboratory Standards. *User Evaluation of Precision Performance of Clinical Chemistry Devices; Tentative Guideline*. Villanova, Pa.: NCCLS; 1984. NCCLS publication EP5-T.

6. National Committee for Clinical Laboratory Standards. *Meeting CLIA Quality Standards in the '90s*. Villanova, Pa.: NCCLS; 1992.

4.0 **Safety**

< TABLE OF CONTENTS

Safety

R

4.1 Introduction

The Occupational Safety & Health Administration (OSHA) ruled that beginning March 6, 1992, all labs must undergo training to protect the workers from bloodborne pathogens. The new regulations outline in detail what employees must be taught about the hazards of working with potentially infectious materials and what precautions must be taken to prevent or minimize exposure. All biosafety training must be documented with dates, summary of content per each class, names and qualifications of all instructors, and the names and job titles of employees who attend.[1]

OSHA has also required that as of May 5, 1992, every employer will have a written plan designed to eliminate or minimize worker exposure. This includes an outline of the employer's hepatitis B vaccination program. Employers are required to offer, at their expense, a vaccine to any worker who may at any time be exposed to potential infectious materials. Staff members may waive their right to the vaccine by signing a form, but they are entitled to change their minds and receive the vaccine as soon as possible.[1]

You may use this section to file any training material, forms, or guidelines regarding lab safety practices. For further information or to obtain training material regarding these regulations, contact OSHA.

Reprints of the final rule, "Occupational Exposures to Blood Borne Pathogens," can be obtained by contacting this organization:

OSHA Office of Publications
U.S. Department of Labor
P.O. Box 37535
Washington, DC 20013-7535
Web site: www.osha.gov

Another excellent source of reference is the National Committee for Clinical Laboratory Standards (NCCLS). The NCCLS is a U.S. organization developing standards for clinical laboratory testing. For further information, you may contact this organization:

National Committee for Clinical Laboratory Standards
940 West Valley Road, Suite 1400
Wayne, PA 19087-1898
610-688-0100, FAX 610-688-0700
e-mail: exoffice@nccls.org
Web site: www.nccls.org

I

4.2 Reference(s) and Bibliography

1. Brown JW, Blackwell H. Complying with the new OSHA regs on HIV and HBV protection. *Medical Laboratory Observer* June 1992; 21.

I For Information Only R Recommended O Optional Information

5.0 **Training**

< TABLE OF CONTENTS

Training

5.1 Introduction

In the *Master Forms* section of this manual, Cholestech has included various forms to support your training requirements.

5.2 Cholestech LDX Training Checklist

This checklist is designed to assist the trainer in training users of the Cholestech LDX System. There is room to date and sign each procedure as the task is completed.

5.3 Certificate of Training—Fingerstick Blood Collection

This certificate can be used to document that fingerstick training has been completed and approved by a physician. You can file the certificates in this section as proof of documented training if it is required by regulations in your area.

5.4 Online Training

Training is available at the Cholestech Web site: www.cholestech.com.

I For Information Only R Recommended O Optional Information

6.0 Material Safety Data Sheets

< TABLE OF CONTENTS

Material Safety Data Sheets

OSHA requires all businesses that manufacture chemical-based products and distribute them through interstate shipment to have a Material Safety Data Sheet (MSDS).

The information contained on an MSDS describes any potential hazards and any special handling required for chemical products.

The standard format for an MSDS is as follows:

1. Identity
2. Hazardous Ingredients
3. Physical Data
4. Fire & Explosion Data
5. Health Information
6. Reactivity Data
7. Spill or Leak Procedures
8. Personal Protection Information
9. Special Precautions

An MSDS for the Cholestech LDX test cassette product is included here.

I For Information Only R Recommended O Optional Information

MATERIAL SAFETY DATA SHEET

CHOLESTECH

SECTION 1 – IDENTITY

NAME		ADDRESS
Cholestech LDX® System		3347 Investment Blvd., Hayward, CA 94545
TELEPHONE NUMBER	**FOR ADDITIONAL INFORMATION CONTACT**	**DATE PREPARED**
800-733-0404	Technical Service	August 25, 1995
COMMON NAME (USED ON LABEL)		**CHEMICAL FAMILY**
Cholestech LDX TC Cassette, TC and HDL Panel Cassette, Lipid Profile Cassette, TC/HDL/GLU Panel Cassette, Lipid Profile plus Glucose Cassette, TC and Glucose Cassette, Cholestech LDX Alanine Aminotransferase and Aspartate Aminotransferase Test Cassette		Does not apply
CHEMICAL NAME		**FORMULA**
Does not apply		Does not apply
TRADE NAME & SYNONYMS		
Cholestech LDX®, Trademark of Cholestech Corporation		

SECTION 2 – HAZARDOUS INGREDIENTS

HAZARDOUS COMPONENT	CAS #	% (wt)	TLV	PEL
None				

PEL: Permissible Exposure Limit established by the Occupational Safety & Health Administration (OSHA).
TLV: Threshold Limit Value established by the American Conference of Governmental Industrial Hygienists, 1987–88.

SECTION 3 – PHYSICAL DATA

BOILING POINT		SPECIFIC GRAVITY	VAPOR PRESSURE
Not determined		($H_2O = 1$) Not determined	(mm Hg) Not determined
PERCENT VOLATILE BY VOLUME (%)	**VAPOR DENSITY (AIR=1)**		**EVAPORATION DATE (_____ - 1)**
Not determined	Not determined		Not determined
SOLUBILITY IN WATER			**REACTIVITY IN WATER**
Some components are soluble			Not determined
APPEARANCE AND ODOR			
White, no odor			

SECTION 4 – FIRE AND EXPLOSION DATA

FLASH POINT	FLAMMABLE LIMITS IN AIR (% by VOLUME)
Not determined	LOWER: Not determined UPPER: Not determined
EXTINGUISHING MEDIA	**AUTO IGNITION TEMPERATURE**
Use extinguishing media appropriate for surrounding fire	Not determined
UNUSUAL FIRE AND EXPLOSION HAZARDS	
Not determined	
SPECIAL FIRE-FIGHTING PROCEDURES	
None	

Continued on next page.

MATERIAL SAFETY DATA SHEET CONTINUED

CHOLESTECH

SECTION 5 – HEALTH INFORMATION

PRIMARY ROUTES OF EXPOSURE

Skin

SIGNS AND SYMPTOMS OF EXPOSURE

(1) ACUTE OVEREXPOSURE – None

(2) CHRONIC OVEREXPOSURE – None

MEDICAL CONDITIONS GENERALLY AGGRAVATED BY EXPOSURE

None

CHEMICAL/COMPONENT LISTED AS CARCINOGEN OR POTENTIAL CARCINOGEN	NTP	IARC	OSHA
None	___ Yes ___ No	___ Yes ___ No	___ Yes ___ No

OTHER EXPOSURE LIMITS

None

EMERGENCY & FIRST AID PROCEDURES

None

SECTION 6 – REACTIVITY DATA

STABILITY	CONDITIONS TO AVOID
Unstable ___ Stable X	Not determined

INCOMPATIBILITY (MATERIALS TO AVOID)

Not determined

HAZARDOUS DECOMPOSITION PRODUCTS

Not determined

HAZARDOUS POLYMERIZATION	CONDITIONS TO AVOID
May Occur ___ Will Not Occur X	Not determined

SECTION 7 – SPILL OR LEAK PROCEDURES

STEPS TO BE TAKEN IN CASE MATERIAL IS LEAKED OR SPILLED

Not applicable

WASTE DISPOSAL METHOD

Dispose of wastes in accordance with federal, state, and local codes

SECTION 8 – PERSONAL PROTECTION INFORMATION

RESPIRATORY PROTECTION

Not required under normal and intended uses

VENTILATION

General room ventilation

PROTECTIVE GLOVES	EYE PROTECTION
Not required	Not required

OTHER PROTECTIVE CLOTHING OR EQUIPMENT

None

SECTION 9 – SPECIAL PRECAUTIONS

PRECAUTIONS TO BE TAKEN IN HANDLING & STORING

Store and handle according to packaged instructions

OTHER PRECAUTIONS

None

< TABLE OF CONTENTS

7.0 **Proficiency Testing**

< TABLE OF CONTENTS

Proficiency Testing

O

7.1 Overview of Proficiency Testing

Under CLIA '88, all laboratories conducting tests classified moderately complex and highly complex must participate in an approved proficiency testing (PT) program for each specialty they perform testing in.

The purpose of this section is to discuss the importance of proficiency testing and describe how proficiency testing is performed. When choosing the appropriate agency for your testing, it is important to ask the agency if it is certified by CMS (Centers for Medicare and Medicaid Services) to comply with CLIA '88 standard regulations.

What Is Proficiency Testing?

Although analyzing quality control specimens provides an "internal" check on the quality of a laboratory's results, proficiency testing serves as an "external" check. Outside agencies send "unknown" specimens to subscribing laboratories. The laboratory performs the required tests and returns the results to the agency. The data are analyzed and a summary report is sent to the laboratory indicating the laboratory's performance.

Why Is Proficiency Testing Necessary?

Proficiency testing assures the user of quality results and measures the performance of the test system and operators relative to other laboratories using the same test system or a reference method.

Testing may identify bias in a test system, which may not be apparent with an internal daily quality control program.

Proficiency testing may be necessary for compliance with state or federal law (e.g., CLIA '88).

How Does Proficiency Testing Work?

Proficiency testing is one aspect of a quality assurance program. The method works in conjunction with a daily internal quality control program. When properly controlled, it indicates the laboratory's accuracy performance on the test system being evaluated.

A number of agencies offer proficiency testing surveys. The surveys vary by the analytes offered for testing, number of challenges per analyte, number of mailings per year, report format, sample preparation and result evaluation.

1. Surveys are offered for most routine tests performed.

2. Under CLIA '88, proficiency testing is required three times per year, testing five samples each time.

3. The specimen of choice for the Cholestech LDX System is a specimen of human serum with no stabilizers.

   The type of specimen provided presents a potential problem for some instruments and methodologies. Lyophilized serum has been the most frequently used sample for clinical chemistry proficiency surveys. But with some test systems, including the Cholestech LDX, lyophilized serum may not provide an adequate accuracy check due to matrix interference. If you are unfamiliar with the concept of matrix effect, please call Cholestech Technical Service for clarification.

   In Section 7.2 of this manual, a list of agencies offering CMS-approved proficiency surveys is provided. The agencies set in bold are the ones Cholestech has evaluated and found to demonstrate acceptable performance on the Cholestech LDX. For testing other instruments in your laboratory, it is important to contact the manufacturer and request the names of agencies that run compatible surveys with no matrix interferences on these instruments or system.

4. The survey samples are mailed to the participating laboratories according to a schedule set by the proficiency testing agency. Within the time limit set by the agency, the laboratory personnel perform the required tests on the survey specimens. *Only tests performed in the laboratory should be analyzed. Survey specimens are handled and analyzed using the same procedure as that for patient specimens.* **When you perform proficiency tests (on the Cholestech LDX) using serum or plasma samples, the Serum switch must be *on.* Refer to the Cholestech LDX System User Manual for instructions to reconfigure the menu from Whole Blood to Serum.**

5. Results on the survey specimens are entered on a preprinted form, coded according to reagent-instrument method and returned to the proficiency testing agency.

   - After evaluation statistics have been calculated, a summary report of results is sent to all participating laboratories.
   - Laboratories may also request that a proficiency testing agency send a copy of its results to state or federal regulatory agencies.
   - In general, regulatory agencies require documented evidence of corrective action taken when survey results fall outside acceptable limits. The director of a point-of-care laboratory will review all proficiency testing results and document the review and responses to unacceptable results.
   - Cholestech Technical Service can provide assistance in troubleshooting proficiency testing failures.

7.2 Proficiency Testing Agencies

- **Wisconsin State Laboratory of Hygiene, Proficiency Testing Program; 465 Henry Mall Room GCD, Madison, WI 53706-1578, 800-462-5261/FAX 608-265-1111.***
- **The College of American Pathologists, EXCEL Program; 325 Waukegan Road, Northfield, IL 60093-2750, 800-323-4040.***
- **American Proficiency Institute; 1159 Business Park Drive, Traverse City, MI 49686, 800-333-0958/FAX 231-941-7287.***
- The American Academy of Family Physicians; AAFP-PT, 11400 Tomahawk Creek Parkway, Leawood, KS 66211-2672, 800-274-7911 (Ask for AAFP-PT)/FAX 816-361-8167.
- Some state health departments.

* These laboratories have been shown to correlate with minimal matrix effects on the Cholestech LDX.

7.3 Reference(s) and Bibliography

1. National Committee for Clinical Laboratory Standards. *Physician's Office Laboratory Guidelines; Tentative Guidelines*. Villanova, Pa.: NCCLS; 1989. NCCLS publication POL1-T.
2. Howanitz PJ, Howanitz JH. *Laboratory Quality Assurance*. New York, N.Y.: McGraw-Hill Book Co; 1987.
3. How to avoid dangerous mistakes in a physician's office laboratory. Continuing Education Course No. 328, American Academy of Family Physicians Scientific Assembly; 1989.

8.0 **Glossary of Terms**

< TABLE OF CONTENTS

Glossary of Terms

Acceptable Control Range – range of results that indicate adequate performance when analyzing a control sample. The range is shown in the control's product insert.

Accuracy – correctness; freedom from error. The accuracy of results can be measured by comparing them with those from another laboratory (this is "*relative accuracy*").

Additive – chemical added to a blood collection tube, usually to prevent the blood from clotting (anticoagulant).

Aerosol – fine mist that solid or liquid particles are dispersed in.

Agglutination – clumping together of antigen-bearing cells, bacteria, or particles in the presence of specific antibodies. Also called "*clumping*."

Aliquot – small portion of a measured volume of a substance taken as a sample representing the whole.

Analysis – laboratory procedure that enables measurement of the amount of an analyte in a specimen.

Analyte – substance or constituent being measured (*e.g.,* cholesterol, triglycerides, glucose).

Antibody – substance formed in the body in response to a foreign substance (an *antigen*) and that interacts only with that substance.

Anticoagulant – chemical used to prevent blood from clotting.

Antigen – any substance that, injected into an organism, causes the development of antibodies.

Antiserum – serum that contains antibodies.

Aseptic – free from infection or septic material; sterile.

Assay – measurement of the amount of an analyte in a specimen; a test.

Autoclave – instrument that sterilizes material by subjecting it to steam under pressure.

Bias (inaccuracy) – measure of the departure from accuracy. A numerical difference between the mean of a set of replicate measurements and the true value of the sample.

Calibrated – (of a measuring device, *e.g.,* a pipette) graduated into appropriate units.

Calibration – taking readings from an instrument or other measuring device and relating them to known concentrations of an analyte or true value.

Calibrator – material, solution, or freeze-dried preparation used in calibration. The concentration of the analytes in a calibrator is known to be within a particular range. Calibrators may be a primary or a secondary standard.

Capillary – any one of the small vessels that form a network throughout the body for the interchange of substances between the blood and tissue fluid.

Capillary (capillary action) – attraction between a liquid and a solid that causes the liquid to rise, as for example, into a capillary tube.

Centrifuge – instrument that separates the lighter portions of a solution, mixture, or suspension from the heavier portions by centrifugal force.

Coagulation – how various coagulation factors in the blood interact to form a clot.

Coefficient of Variation – statistical measure of the ratio of the standard deviation of a series of measurements to the mean of the measurements. Expressed as a percentage, the coefficient of variation (CV) shows the precision of measurements.

Colorimeter – measurement and analysis of color by comparison with a standard in terms of brightness, hue, or purity.

Contaminant – microorganism, chemical, or other material that makes something impure by contact or mixture with it.

Control – material, solution, lyophilized preparation, or pool of collected serum designed to be used in the process of quality control. The concentrations of the analytes of the interest in the control material are known within limits ascertained during its preparation, and confirmed in use.

Data – numerical or quantitative results of a test that conclusions are made from.

Diagnostic Test – laboratory test or measurement that helps determine the cause or nature of a disease. Laboratory tests are often called "*in vitro* diagnostic tests."

Diluent – liquid (usually distilled water) used to reconstitute a freeze-dried control or reagent.

Dilution – mixing of a diluent and a calibrator, or control, or patient sample. A serial dilution is the progressive dilution of a substance in a series of tubes in predetermined ratios.

ELISA – enzyme-linked immunosorbent assay; a diagnostic test used to detect either antigens or antibodies in a patient's specimen.

Enzyme – compound produced in a cell and capable of greatly increasing the rate of a chemical reaction.

Erythrocyte – red blood cell, one of the elements in peripheral blood.

Etiologic Agent – agent that causes disease.

False Negative (Result) – negative test result for a patient who is positive for the condition or constituent in question.

False Positive (Result) – positive test result for a patient who is negative for the constituent or condition in question.

Glycolysis – lowering of glucose concentration in a blood sample by the action of enzymes in the red blood cells.

Gravimetry – measurement of a substance by determining its weight or specific gravity.

Hematoma – mass of blood, usually clotted, under the skin in an organ, space, or tissue caused by a break in the wall of a blood vessel.

Hematocrit – (also called *packed cell volume*) volume percentage of erythrocytes (red blood cells) in whole blood.

Hemolysis – (adjective *hemolytic*) breakdown of red blood cells in serum or plasma, freeing the hemoglobin from the cells. When this happens, the serum or plasma becomes reddish. Hemolysis interferes with some laboratory tests. *Beta hemolysis* is the production of a clear zone surrounding a bacterial colony on blood-agar medium, which is characteristic of certain pathogenic bacteria such as Group A *Streptococcus*.

Icterus – (adjective icteric) condition in which there is too much bilirubin in the blood; jaundice. An icteric serum sample looks dark yellow (it may even look greenish). An icteric sample may produce erroneous test results.

Immunoassay – diagnostic test that uses a specific antibody or antigen to detect the presence of an analyte.

Inaccuracy – see *Bias.*

In Control – in a testing procedure when the results from a control sample or series of control samples are within the acceptable control range.

Infectious Agent – any microorganism that can invade body tissue and multiply, causing infection.

In Vitro – Latin for "in glass," used to describe diagnostic tests that analyze processes occuring inside the body (*in vivo*) from samples of body fluids in glass (test tubes) or other controlled artificial environments.

Levey-Jennings Chart – quality control chart; a graph or table that shows results of control tests over a period of time; used in a quality control program.

Linearity – measure of the range (the *linear range*) of concentration of an analyte over which a measure or test produces consistent (*i.e.,* linear, straight line) and accurate results.

Lipemia – (adjective *lipemic*) condition of too much fat or lipids in the blood. A lipemic serum sample looks milky and turbid, and may produce erroneous results.

Lyophilized – freeze-dried; a lyophilized calibrator, control, or reagent has been specially dried to make its analytes more stable. It must be refrigerated to maintain its stability, and is reconstituted by adding an appropriate diluent.

Matrix – physical and chemical properties that describe a fluid. Often used to describe the effect of differences seen when lyophilized (freeze-dried) samples, such as control material, behave differently than patient specimens when analyzed.

Mean – average of the numerical results obtained from a series of analyses.

Method – analytical method; the instructions including procedures, material, equipment, and everything else needed for an analyst to perform an analysis.

Normal Values (Expected Values, Reference Values) – range of values established for each analyte, which includes the results expected when performing a test on a healthy person.

Out of Control – in a testing procedure when the results from a control sample are outside the acceptable control range.

Pathogen – (adjective *pathogenic*) microorganism that causes a disease.

Phlebotomy – puncture of a vein to collect blood. A *phlebotomist* collects blood by venipuncture (venous blood).

Photometry – measurement or analysis of light emitted by a substance. *Reflectance photometry* is the principle used in most instruments that read dry reagent strips.

Pipette – glass or transparent plastic tube used to measure small quantities of liquid. A *volumetric pipette* is an extremely accurate, single-line pipette used to reconstitute calibrators and controls.

Plasma – liquid part of blood after it has been mixed with an anticoagulant and spun down in a centrifuge.

Precision (reproducibility) – measure of the closeness of the results obtained when analyzing the same sample more than once; the measure of agreement between replicate measurements.

Procedure Manual – laboratory manual that contains the methods, materials, and other information needed to do a test.

Product Insert – informational material that comes with instruments, reagents, and other laboratory products giving instructions for the use of the product and other information required of the manufacturer by the U.S. Food and Drug Administration.

Proficiency Samples – analytes of unknown concentration that are sent to laboratories participating in proficiency testing programs.

Proficiency Testing – program in which samples are sent to a group of laboratories for analysis. The results are tabulated by the program's sponsor, and a participating laboratory can compare its results with those of other laboratories that use the same method.

Protocol – standard set of procedures for performing a procedure, such as a test or an evaluation.

Quality Assurance – comprehensive set of policies, procedures, and practices necessary to make sure that the laboratory's results are reliable. QA includes record keeping, calibration, and maintenance of equipment, quality control, proficiency testing, and training.

Quality Control – set of laboratory procedures designed to ensure that the test method is working properly and that the results meet the diagnostic needs of the physician. QC includes testing control samples, charting the results, and analyzing them statistically.

Quantitative – applied to tests that give results expressing the numerical amount of an analyte in a specimen. This is in contrast to qualitative tests that detect whether a particular analyte, constituent, or condition is present.

Reactivity – ability of a reagent to produce its proper chemical reaction. Reagents can lose their reactivity if they are misused, mishandled, or are too old.

Reagent – substance that produces a chemical reaction in a sample that allows an analyte to be detected and measured.

Reconstitute – to add a diluent to a freeze-dried calibrator, control, or reagent.

Reference Interval – see *Normal Values.*

Replicate – to repeat an experiment and/or analysis to check the accuracy of the results. Each repeat is a replicate (pronounced *rep*-li-kit) test or measurement.

Reproducibility – see *Precision*.

Result – value obtained by analysis for a particular analyte in a particular sample.

Run (analytical run) – group of measurements by a particular method over a period of time during which the accuracy and precision of the method are expected to be stable.

Sample – part of a specimen used for an analysis.

Sensitivity – ability of a test to give a positive result for patients who have the disease or condition they are tested for; measured as the ratio of positive tests to the total number of tests in those who have the disease; expressed as a percentage.

Serum – liquid part of the blood after it has coagulated and then been spun down in a centrifuge.

Specificity – ability of a test to give a negative result for patients who do not have the disease or condition they are tested for; measured as the ratio of negative tests to the total number of tests in those who do not have the disease or condition; expressed as a percentage.

Specimen – portion of body fluid (e.g., blood or urine) collected from the patient.

Split-Sample Testing – dividing a sample in half, and testing half in your laboratory and having the other half tested in another laboratory, and then comparing the results. This is a technique for testing accuracy.

Stability – ability of a specimen, reagent, or control to maintain a constant concentration of the analyte. Reagents and controls must be handled and stored properly and used before their expiration dates to maintain their stability. Specimens must be collected, handled, and processed properly.

Standard, Primary – reference material of fixed and known chemical composition and capable of being prepared in essentially pure form. Also: any certified reference material generally accepted or officially recognized as the unique standard for the assay regardless of its level of purity of analyte content.

Standard, Secondary – reference material, the analyte concentration of which has been ascertained by reference to a primary standard.

Standard Deviation – statistical measurement of the degree of variation from the mean of a series of measurements. It is a measure of precision or reproducibility.

Test – procedure for detecting the presence or amount of an analyte.

Titer – quantity of a substance required to produce a reaction with a particular amount of another substance. The amount of one substance required to correspond with a particular amount of another substance. *Agglutination titer* is the highest dilution of a serum that causes clumping of particulate antigens.

Throughput – applied to analytical instruments specifying the number of tests that can be performed in a given time.

Toxicology – study of the origin, nature, and effects of poison. Toxicological analyses are used to detect the amount of a substance that can be poisonous at a particular concentration.

Turbidity – (adjective *turbid*) cloudiness; distribution of a substance in a solution, making it unclear or cloudy.

Value – number, in units of the method, obtained for an analyte in a particular sample. See *Result*.

Venipuncture – procedure for collecting a blood sample from a vein (“venous blood”).

Whole Blood – blood mixed with an anticoagulant but not spun down in a centrifuge.

8.1 Reference(s) and Bibliography

1. National Committee for Clinical Laboratory Standards. *Physician’s Office Laboratory Procedure Manual; Tentative Guideline*. Villanova, Pa.: NCCLS; 1989. NCCLS publication POL2-T, Vol. 12, No. 5.

9.0 **Master Forms**

< TABLE OF CONTENTS

OPTICS CHECK LOG

Cholestech LDX®

Cholestech LDX Serial No. **Acceptable Range**

Optics Check Cassette Lot No. **Expiration Date**

DATE	RESULTS				PERFORMED BY	ACCEPT	REJECT	COMMENTS
	Ch.1	Ch.2	Ch.3	Ch.4				

< TABLE OF CONTENTS

TEMPERATURE CHART

YEAR

Record the temperature and initial the space provided. One sheet should be used per room, refrigerator, or freezer as *your* procedures dictate.

Site ID **Acceptable Temperature Range**

	JAN	FEB	MARCH	APRIL	MAY	JUNE	JULY	AUG	SEPT	OCT	NOV	DEC
1												
2												
3												
4												
5												
6												
7												
8												
9												
10												
11												
12												
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31												

< TABLE OF CONTENTS

INSTRUMENT HISTORY RECORD

Cholestech LDX®

GENERAL INFORMATION

Instrument			
Model No.	Serial No.		
Date Purchased	Cost		
Manufacturer			
Address	City	State	Zip
Telephone	Contact Person:		
Distributor			
Address	City	State	Zip
Telephone	Contact Person		
Warranty	Contact Person		
Notes			
Technical Service Representative		Telephone	

SERVICE RECORD

Date	Comments

< TABLE OF CONTENTS

INFORMATION AND SERVICE LOG

Cholestech LDX®

Instrument Serial No. Purchase Date Warranty Expires

Customer Service Representative Phone No.

Technical Service Representative Phone No.

Sales Representative Phone No.

DATE	PROBLEM	ACTION TAKEN	OPERATOR

< TABLE OF CONTENTS

INITIAL SETUP CHECKLIST

Cholestech LDX®

Cholestech LDX Serial No. **Date of Setup**

Name of Lab Person Performing Initial Setup

Signature Approval by Laboratory Director

FACILITY SPECIFICATIONS	OPERATOR	DATE
1. Room temperature: 68–87°F (20–31°C)		
2. Stable work surface free from vibrations		
3. Isolation from direct heat and light sources (e.g., sunlight, ovens, room heater, etc.)		
4. A grounded wall outlet supplying 100 to 240 VAC with the appropriate power supply, which will not be interrupted during use.		
INSTALLATION		
1. Verify that the wall outlet corresponds to the voltage requirements of the power supply.		
2. Connect the power cord to the inlet on the back of the instrument.		
3. Plug the power supply into the wall socket.		
4. Allow the instrument to warm up for five minutes.		
5. The Liquid Crystal Display (LCD) will give the message: SELFTEST RUNNING		
6. The LCD will give the message: SELFTEST OK		
7. Allow up to five minutes for initial warm-up. The LCD will give the message: INITIAL WARM UP**********		
8. LCD screen is blank and the system is warmed up and ready for use.		
9. Set the Configuration Menu.		
10. Press **RUN** to begin testing.		
NOTES		

< TABLE OF CONTENTS

EQUIPMENT MAINTENANCE / CLEANING LOG

Cholestech LDX®

INSTRUMENT NAME					MAINTENANCE NOTES (problems reported, dates, solutions)
Serial No.	Quarterly Cleaning Schedule Dates				

INSTRUMENTS IN-USE RECORD

INSTRUMENT/ MODEL	SERIAL NUMBER	MANUFACTURER	DATE INSTALLED	OPERATOR

< TABLE OF CONTENTS

PATIENT RESULT LOG

Cholestech LDX®

Cassette Lot No. Expiration Date Cholestech LDX Serial No.

DATE	OPERATOR	PATIENT NAME	PATIENT ID	TC	TRG	GLU	HDL	LDL	TC/HDL	ALT	AST	non-HDL

< TABLE OF CONTENTS

PATIENT RESULT LABEL LOG NO. 1

Cholestech LDX®

Cholestech LDX Serial No. _____ Operator _____

Cassette Lot No. _____ Expiration Date _____

Place Label Here	Place Label Here
Place Label Here	Place Label Here
Place Label Here	Place Label Here
Place Label Here	Place Label Here
Place Label Here	Place Label Here
Place Label Here	Place Label Here

< TABLE OF CONTENTS

PATIENT RESULT LABEL LOG NO. 2

Cholestech LDX®

Cholestech LDX Serial No. Operator

Cassette Lot No. Expiration Date

Place Label Here	Place Label Here	Place Label Here
Place Label Here	Place Label Here	Place Label Here
Place Label Here	Place Label Here	Place Label Here

< TABLE OF CONTENTS

QUALITY CONTROL LOG NO. 1

Cholestech LDX®

Cholestech LDX Serial No.	**Control Range**	TC	HDL
Control Lot		TRG	GLU
Expiration Date		ALT	AST
Control Level			

DATE	CASSETTE LOT NO.	ANALYTE	VALUE	ACCEPT	REJECT	OPERATOR	COMMENTS / ACTION TAKEN

< TABLE OF CONTENTS

QUALITY CONTROL LOG NO. 2

Cholestech LDX®

Cholestech LDX Serial No.	**Level 1 Control**	Lot #		**Level 2 Control**	Lot #
Optics Check Lot No.		Exp. Date			Exp. Date
Optics Check Exp. Date		Open Exp. Date			Open Exp. Date
Optics Check Range	**Level 1 Ranges**	TC	HDL	**Level 2 Ranges**	TC HDL
		TRG	LDL		TRG LDL
		non-HDL	TC•HDL		non-HDL TC•HDL
		GLU	AST		GLU AST
		ALT	AST•ALT		ALT AST•ALT

DATE	OPTICS Performed Each Day of Use				QUALITY CONTROL Test with each new shipment and/or each new lot									
	Ch. 1	Ch. 2	Ch. 3	Ch. 4	TC	HDL	TRG	LDL	non-HDL	TC•HDL	GLU	AST	ALT	AST•ALT

< TABLE OF CONTENTS

QUALITY ASSURANCE RECORD

Cholestech LDX®

DATE	Control Level 1 Lot No.						Expiration Date		
OPERATOR	Control Level 2 Lot No.						Expiration Date		
	Cassette Type			Lot No.			Expiration Date		
ROOM TEMP	CONTROL RANGES	TRG	TC	GLU	HDL	ALT	AST		
REFRIG TEMP	Level 1 (mg/dL)	–	–	–	–	–			
	Level 2 (mg/dL)	–	–	–	–	–			
CHOLESTECH LDX SERIAL NO.	CONTROL RESULTS	TRG	TC	GLU	HDL	ALT	AST	Accept	Reject
	Level 1								
	Level 2								

DATE	Control Level 1 Lot No.						Expiration Date		
OPERATOR	Control Level 2 Lot No.						Expiration Date		
	Cassette Type			Lot No.			Expiration Date		
ROOM TEMP	CONTROL RANGES	TRG	TC	GLU	HDL	ALT	AST		
REFRIG TEMP	Level 1 (mg/dL)	–	–	–	–	–			
	Level 2 (mg/dL)	–	–	–	–	–			
CHOLESTECH LDX SERIAL NO.	CONTROL RESULTS	TRG	TC	GLU	HDL	ALT	AST	Accept	Reject
	Level 1								
	Level 2								

DATE	Control Level 1 Lot No.						Expiration Date		
OPERATOR	Control Level 2 Lot No.						Expiration Date		
	Cassette Type			Lot No.			Expiration Date		
ROOM TEMP	CONTROL RANGES	TRG	TC	GLU	HDL	ALT	AST		
REFRIG TEMP	Level 1 (mg/dL)	–	–	–	–	–			
	Level 2 (mg/dL)	–	–	–	–	–			
CHOLESTECH LDX SERIAL NO.	CONTROL RESULTS	TRG	TC	GLU	HDL	ALT	AST	Accept	Reject
	Level 1								
	Level 2								

< TABLE OF CONTENTS

CONTROL RANGE CALCULATION FORM

Cholestech LDX®

Control Name | **Lot No.** | **Analyte**

Cassette Lot No. | **Cholestech LDX Serial No.**

☐ **Accept** ☐ **Reject** | **Director Approval** | **Approval Date**

1	2	3	4	5	6
No.	**Date**	**Init.**	**Result**	**Result – $\bar{X}$**	**(Result – $\bar{X}$)²**
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					
13					
14					
15					
16					
17					
18					
19					
20					
SUM (∑)					

NOTES

1. Record the date in Column 2 and the initials in Column 3.
2. Record the results of the quality control material in Column 4 – RESULT.
3. Calculate the MEAN ($\bar{X}$): Add the values (Column 4) in the RESULT Column then divide by the number of results (n):

$$\text{MEAN } (\bar{X}) = \frac{\Sigma \text{ Results}}{n}$$

4. Calculate the difference between each RESULT and the MEAN ($\bar{X}$) and record in Column 5 (RESULT – $\bar{X}$).
5. Square each value in Column 5 and record in Column 6 (RESULT – $\bar{X}$)².
6. Add the values in Column 6.
7. Calculate the standard deviation (SD) using the formula:

(Divide the sum of the values calculated in Column 6 by the number of values minus 1. Take the square root of this number.)

$$SD = \sqrt{\frac{\Sigma (\text{Results} - \bar{X})^2}{n - 1}}$$

8. The control range is the MEAN ($\bar{X}$) ± 2SD, record above.

< TABLE OF CONTENTS

ACCURACY STUDY DATA

Operator

Analyte

Cholestech LDX Serial No.

Cassette Lot No.

Cassette Expiration Date

	REFERENCE METHOD			CHOLESTECH LDX			
	Sample	Date	Reference Method	1	2	$\bar{X}$	% Difference
1							
2							
3							
4							
5							
6							
7							
8							
9							
10							

Acceptable Accuracy Range is ± ____ %

$$\% \text{ Difference} = \frac{\text{Cholestech LDX Result} - \text{Ref. Result}}{\text{Ref. Result}} \times 100$$

Test Disposition ☐ Accept ☐ Reject

Director Approval

Approval Date

< TABLE OF CONTENTS

PRECISION CALCULATION FORM (WITHIN-RUN)

Cholestech LDX®

Date **Operator** **Specimen Identification** **Analyte**

Cassette Lot No. **Cholestech LDX Serial No.**

☐ **Accept** ☐ **Reject** **Director Approval** **Approval Date**

1	2	3	4
No.	**Result**	**Result – $\bar{X}$**	**(Result – $\bar{X}$)²**
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			
11			
12			
13			
14			
15			
16			
17			
18			
19			
20			
SUM (∑)			
NOTES			**$\bar{X}$ =**
			SD =
			%CV =

1. Record the result of the quality control material in Column 2 – RESULT.

2. Calculate the MEAN ($\bar{X}$): Add the values (Column 2) in the RESULT Column then divide by the number of results (n):

$$\text{MEAN } (\bar{X}) = \frac{\Sigma \text{ Results}}{n}$$

3. Calculate the difference between each RESULT and the MEAN ($\bar{X}$) and record in Column 3 (RESULT – $\bar{X}$).

4. Square each value in Column 3 and record in Column 4 (RESULT – $\bar{X}$)².

5. Add the values in Column 4.

6. Calculate the Standard Deviation (SD) using the formula:

(Divide the sum of the values calculated in Column 4 by the number of values minus 1. Take the square root of this number.)

$$SD = \sqrt{\frac{\Sigma (\text{Results} - \bar{X})^2}{n - 1}}$$

7. To calculate the coefficient of variation (%CV), use the following formula:

$$\%CV = \frac{SD}{\bar{X}} \times 100$$

< TABLE OF CONTENTS

TRAINING CHECKLIST

Cholestech LDX®

Name

Director Signature **Date Approved**

PREPARATION	BY	DATE
1. Has read User Manual.		
2. Has read Procedure Manual.		
3. Has viewed Cholestech LDX Training Video.		
4. Has read Cholestech product insert.		
5. Understands refrigerated and room temperature storage procedures for test cassettes.		
6. Has been properly trained in procedure for handling biohazardous waste.		
THE CHOLESTECH LDX ANALYZER		
7. Correctly connects the Analyzer to the power supply.		
8. Correctly connects the Analyzer to the printer (if applicable).		
9. Understands and demonstrates Analyzer functions:		
– RUN, STOP, DATA buttons		
– Configuration Menu		
– Risk Assessment Program		
10. Demonstrates correct procedure for changing ROM Pack.		
11. Understands the meaning of all LCD display messages.		
12. Demonstrates how to clean Analyzer case and cassette holder tray.		
QUALITY ASSURANCE		
13. Correctly performs the optics check procedure.		
14. Correctly performs the quality control procedure.		
15. Understands what actions are to be taken if the quality control results are outside acceptable limits.		
16. Understands Proficiency Testing.		
17. Understands appropriate record keeping: QC, patient logs, temperature monitoring, etc.		
PERFORMING A TEST		
18. Allows test cassettes to come to room temperature prior to running test.		
19. Properly prepares supplies for patient testing: alcohol swabs; gauze; lancets; capillary tubes/plungers; latex gloves; biohazardous waste container.		
20. Explains the procedure to the patient.		
21. Handles cassette properly.		
22. Performs fingerstick using correct techniques.		
23. Performs test properly.		
24. Records results.		

NOTES

< TABLE OF CONTENTS

Certificate of Training

for Fingerstick Blood Collection

I, Dr. _____ , certify that _____

possesses the necessary skills and competencies to perform skin puncture for fingerstick blood collection.

This person has properly demonstrated to me fingerstick blood collection in accordance with currently accepted laboratory standards and protocols. Proper knowledge of the disposal of biohazardous material and industrial safety has been observed and comprehended for subsequent health events.

Authorization herein is limited to any nondiagnostic health program for general health assessment and does not include venipuncture, arterial puncture or any other procedure for obtaining a blood specimen.

Date _____

Physician's Name _____

DEA No. _____

Cholestech LDX®

CHOLESTECH

Cholestech LDX®

System Procedure Manual

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< TABLE OF CONTENTS